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CONSUMER PRODUCT SAFETY COMMISSION

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Establishing Technical Requirements for Toys and Other Articles Intended for Use by Children Under 8 Years of Age

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Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

Technical Requirements for Determining a Sharp Metal or Glass Edge in Toys and Other Articles Intended for Use by Children Under 8 Years of Age

AGENCY: Consumer Product Safety Commission.

ACTION: Final regulation.

SUMMARY: The Commission is issuing a regulation which establishes technical requirements for toys and other articles intended for use by children under 8 years of age. These requirements identify sharp metal or glass edges on such articles that could injure children. If the Commission identifies sharp edges on particular children's articles that present an unreasonable risk of injury to children under 8 years of age, it will initiate rulemaking proceedings to ban those articles.

DATE: The regulation becomes effective on March 26, 1979, and it applies to all products subject to the regulation and introduced into interstate commerce after that date.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

BACKGROUND

On January 7, 1975 the Consumer Product Safety Commission, pursuant to section 2(f)(1)(D) of the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261(f)(1)(D)), proposed for public comment regulations to ban toys intended for children under 8 years of age[1] that present an unreasonable risk of personal injury from avulsion or laceration hazards due to sharp edges (40 FR 1488). The proposed regulations included test criteria for determining whether such toys present these hazards.

Following extensive review of the public comments received, as well as staff reevaluation of the proposal, the Commission withdrew the January 1975 proposal and proposed a new regulation for public comment on September 1, 1977 (42 FR 44160-67).

The primary reason for proposing a new regulation in September 1977 was that the Commission decided not to pursue a regulation of sharp edges on toys that automatically banned all toys not meeting specified technical criteria. Accordingly, the September 1977 proposed regulation was designed to identify toys containing sharp metal or glass edges that the Commission preliminarily believed to be hazardous to children under 8 years of age, but not to ban them automatically.

The final regulation issued below, like the September 1977 proposal, is a technical requirements regulation which preliminarily identifies hazardous toys. The Commission will regulate those toys on a product-by-product basis whenever it believes that they present a mechanical hazard, as defined in the FHSA.

The September 1977 proposal also contained some technical changes that were made to the test method of the January 1975 proposal, including a new set of articulated probes to determine accessibility of sharp edges, clarification of the specifications for the tape that is used with the sharp edge test device, and an adjustment in the force level used in the test procedure.

In addition, the September 1977 proposal applied only to metal and glass edges, while the January 1975 proposal had been applicable to edges made of all materials. The primary reason for this limitation was that the research leading to the sharp edge test procedure evaluated the laceration hazards of metal edges only. The relevant physical properties of glass are sufficiently similar to metal to allow for meaningful application of the research to glass edges. However, the research did not take into account the softness, elasticity, and other properties of plastics and other non-metal materials. Further, the test method that was developed for sharp edges proved to be unsuitable for detecting harzardous edges made of those materials. Edges made of non-metal and non-glass materials were therefore excluded from the September 1977 proposed regulation.

All of the changes were fully discussed in the September 1, 1977 FEDERAL REGISTER document. The provisions of the September 1, 1977 proposal are fully discussed below.

PROPOSED REGULATION

(a) RISK OF INJURY

In issuing the proposed regulation, the Commission found that certain toys intended for children under 8 years of age can tear or cut skin and cause bleeding, during normal use or reasonably foreseeable misuse, and thus present an unreasonable risk of injury. This finding was based in part on the staff's investigation of the sharp edges present on such toys that have been in the marketplace during the past few years.

In addition, the Commission relied on an analysis of toy-related injuries contained in its in-depth investigation reports and reported through its National Electronic Injury Surveillance System (NEISS). NEISS is a computer-based network of 119 statistically-selected hospital emergency rooms throughout the country which transmits injury data to the Commission.

A review of NEISS injury data indicates that a substantial number of children under 8 years of age receive laceration and avulsion injuries in toy-related incidents. In calendar year 1976, for example, an estimated 43,300 children in that age category were treated in hospital emergency rooms for such toy-related injuries.

To determine the extent to which lacerations and avulsions occur from toys intended for children under 8 years of age, the Commission staff divided toys into the following three categories:

a. Toys primarily intended for use by children under the age of 8 years.

b. Toys primarily intended for use by children 8 years to 14 years of age.

c. Toys intended for use by children in both age groups.

Of the estimated 43,300 toy-related laceration and avulsion injuries treated in emergency rooms in 1976, an estimated 9,000 were associated with products intended primarily for use by children under 8 years of age. An additional 30,800 such injuries were associated with products intended for use by children in both the under-8-year and the 8-to-14-year age groups. In addition, based on NEISS estimates, laceration and avulsion injuries accounted for over half (approximately 53 percent) of all toy-related injuries to children under 8 years of age.

By definition, the NEISS-reported injuries which support the need for the technical requirements are serious enough to be treated in hospital emergency rooms. A purchaser of toys for children under 8 years of age certainly does not expect them to cause such injuries to children. While many toy-related laceration injuries may cause only minor bleeding, there are a substantial number of injuries which are more severe. Such injuries warrant the adoption of reasonable regulations to reduce or eliminate their occurrence.

[1] The Commission intends that the scope of the technical requirements regulation issued below will include other articles intended for use by children under 8 years of age, as well as toys. However, in an effort to simplify reading the preamble, the term toy(s) will be used inclusively for both toys and other articles intended for use by children.

In the proposal, the Commission emphasized that the proposed technical requirements were intended to set a standard of safety to reduce the risks of injury not only for the products currently available to young children, but also for the new and redesigned products for which there are no hazard experience data available to the Commission. The Commission estimates that between 3,000 and 5,000 new children's products (of which a large number are intended for children under 8) are introduced into the marketplace each year.

(b) PROCEDURES

On September 1, 1977, the Commission proposed a technical requirements regulation that established criteria for sharp metal and glass edges on toys intended for children under 8 years of age, but did not ban automatically toys failing to meet those criteria. Under this approach, the Commission would regulate such toys on a product-by-product basis whenever they both failed to meet the test criteria and presented a mechanical hazard as defined in the FHSA, in the judgment of the Commission. (The reasons supporting this approach are detailed in the September 1, 1977 FEDERAL REGISTER document.)

If the Commission decided to initiate banning actions against any toys found to be out of compliance with the technical requirements, it could proceed in several different ways. Under relevant provisions of the Administrative Procedure Act (5 U.S.C. 553), which govern regulations issued under sections 2(f)(1)(D) and 3(e) of the FHSA (unless the Commission specifically selects alternative procedures), the Commission cannot ban a toy until it publishes a general notice of proposed rulemaking in the FEDERAL REGISTER. In the alternative, persons subject to the proposed rule could be named and either personally served or otherwise have actual notice of it (5 U.S.C. 553(b)).

Depending upon the individual circumstances of a potential banning situation, the Commission will decide how best to provide the required prior notice to manufacturers and others who are subject to a toy banning regulation. If the timing of a ban is a crucial factor, the Commission may decide that individualized notice to those subject to the proposed rule will best protect the public. Alternatively, if comment from consumers and other members of the public is considered particularly important, the Commission would probably publish a notice in the FEDERAL REGISTER and accept comments for a specified time period.

It may even be that the Commission would first notify a manufacturer of a toy that has failed the test criteria before deciding whether to solicit public comment in a FEDERAL REGISTER banning proposal. All of these options will be open to the Commission when it discovers that a particular toy does not meet the technical requirements and when it decides preliminarily that such a toy presents a mechanical hazard under the FHSA.

In whatever manner the Commission provides the necessary notice of a proposed ban, a toy is not banned unless and until the Commission issues a final regulation classifying the toy as a hazardous substance (and thus a banned hazardous substance) according to sections 2(f)(1)(D), 2(q)(1)(A), and 3(e) of the FHSA.[3] If the Commission decides that a toy that fails to meet the technical requirements does not present a mechanical hazard, the Commission will not initiate action against that toy. For example, the underside of a play pen or other piece of juvenile furniture could have an edge that fails to meet the requirements. Nevertheless, the location of that edge may be such that it would not be hazardous under normal conditions of use and storage.

(c) SHARP EDGE TEST CRITERIA

1. *Test device.* The sharp edge test criteria in the September 1977 proposal relied, to a large extent, on a test device that the National Bureau of Standards (NBS) developed for the Commission.

NBS designed a sharp edge test device to distinguish, on the basis of sharpness, between sharp and dull edges that children can contact during the casual handling of toys. Casual handling includes the range of activity associated with unpacking, handling, operating, and playing with toys including foreseeable misuse and other types of play not intended by the manufacturer.

Under the sponsorship of the Commission and its predecessor agency, the Food and Drug Administration, NBS conducted research on certain aspects of human skin cutting. The results are contained in an NBS report entitled "Some Cutting Experiments on Human Skin and Synthetic Materials", NBSIR 73-262 (October 1973). In the study, tests were performed in which the cutability of excised cadaver skin was examined using "standard edges" of differing edge geometries. The edges for these tests were selected for having typical geometries and varied abilities to cut skin. Skin samples were wrapped around a cylindrical hardwood mandrel that turned a single rotation while the test edge was held stationary and a known force applied. The resultant data were summarized for various force levels and the edges were ranked in order of sharpness.

In another study relied on by the Commission, NBS reported in a document entitled "A Study of the Strength Capabilities of Children Ages Two Through Six", NBSIR 73-156 (August 1973), that the average maximum gripping force for children 5 years of age is 20 pounds. Older children are stronger and attain higher force levels but have a more accurate sense of judgment and are less likely to grasp an object indiscriminately with maximum force.

In addition to the NBS studies, the Commission considered the results of tests on sharp edges performed by the Department of Anatomy at the University of Virginia. The testers evaluated blades, with edges of similar geometries to those used in the NBS tests, for their ability to cut live and dead pigs' skin and cadaver skin, both on the body and excised from the body.

The tests, performed over a range of force levels, did not support any implication that human skin and pigs' skin differ in their resistance to cutting since excised samples of each behaved generally in similar ways in the cutting tests. Skin with subcutaneous tissue removed (as used in the NBS tests) and cadaver skin in place over bone (leg skin over shinbone) showed the least resistance to cutting injury.

In a summary of observations on cuts, the University of Virginia report was able to identify blades with certain edge geometries which are considered sharp since they consistently cut deeply into or through the skin under the application of light forces. Other blades, however, were considered dull because they rarely cut skin unless it was tested with the subcutaneous tissue removed and against a hard backing.

NBS developed a prototype test device for sharp edges in toys which is described in an NBS report entitled "An Inspection Procedure for Detecting Hazardous Edges," NBSIR 74-428 (April 1974). The device is designed to be hand-held, usable in any orientation, and easy to operate. The diameter of the rotating mandrel approximates the size of a child's finger and is wrapped with a simulated skin. Material suitable for use with the test device as the simulated skin is tape made from polytetrafluoroethylene (TFE) which has an adhesive backing to provide for easy mounting on the mandrel. (The tape is discussed below.)

In January 1975 the Commission proposed as part of the test procedure that an edge be applied to the tape-covered mandrel at a force of 3.8 pounds. In response to comments that

[3] An exception is that, under section 3(e)(2) of the FHSA (15 U.S.C. 1262(e)(2)), a toy presenting an "imminent hazard" may be banned immediately by publication of a single notice in the FEDERAL REGISTER.

criticized this force, the Commission conducted some tests on edges taken from toy samples that were reported to have caused laceration injuries to children during normal play. Based on these tests, the Commission proposed in September 1977 that the force be 1.35 pounds. (These tests are fully described in the preamble to the September 1977 proposal at 42 FR 44162.)

2. *Tape.* The characteristics of the tape wrapped around the mandrel of the test device are crucial in distinguishing between sharp and dull edges. Various brands of polytetrafluoroethylene tape have different degrees of cutability. Therefore, the Commission proposed a tape qualifying procedure in January 1975, along with the sharp edge test method it proposed at that time. Certain standard edges which NBS had chosen as sharp and dull edges based on the human skin cutting tests were used to select and qualify the tape, thereby reducing variability in results obtained during actual testing. This would allow several tapes to qualify.

In response to numerous critical comments, however, the Commission included different tape specifications in its September 1977 proposal. The Commission performed additional tests to determine the cutting variability of a single brand of tape from different rolls, as well as the variability within a single role. As a result of these tests, the Commission's proposal specified the use of a single brand of tape known as CHR type "T" TFE tape.

During subsequent testing the Commission found that TFE tape is temperature sensitive and that temperatures above 30° (86° F) could change its cutability characteristics. The September 1977 proposal also included a provision addressed to this circumstance.

3. *Use and abuse.* The testing criteria in the September 1977 proposal involved testing for sharp edges before and after application of the Commission's "use and abuse" test procedures (16 CFR 1500.50–53). These test procedures are intended to expose potential hazards that could result from normal use or the reasonably foreseeable damage or abuse to which toys and games are subjected.

The Commission has concluded that, pending additional staff review, the bite test provisions in the use and abuse regulations (16 CFR 1500.51(c), 52(c), and 53(c)) should not be incorporated into the sharp edge test criteria. The September 1977 proposal reflected this conclusion.

(d) *Accessibility criteria.* The September 1977 proposal included criteria for determining when a sharp edge was sufficiently accessible to present a hazard to children under 8 years of age. Any edge that was inaccessible would not fail to meet the criteria, even if it would be considered sharp by the sharp edge test device.

The proposal specified two articulated probes that were intended to determine accessibility of children's fingers to potentially hazardous edges. The Commission selected the anthropometric measurements[3] of young children for the lengths and the diameters of the small and middle fingers as well as the dimensions for hand clearance. Because children up to the age of 8 years are in a period of rapid growth, the anthropometric measurements were divided into two age groups—0 to 3 years and 3 years to 8 years of age. The two probes correspond to these same age groups.

To insure protection of the greatest number of children in each age group, the Commission selected anthropometric measurements that reflect the following assumptions:

i. That the younger children in each age group have narrower hands and therefore can reach into openings which would be inaccessible to an older child.

ii. That the older children in each age group have longer fingers and therefore can touch the inside components of toys which would be inaccessible to a younger child.

Furthermore, anthropometric data were not available for the dimensions of a child's index finger. Those dimensions have been approximated by averaging the respective dimensions of the small and middle fingers of children in the two age groups.

In the 0 to 3 year age group, measurements for a 5th percentile[4] 3-month-old's small and middle fingers were averaged and used to approximate the diameter of the index finger. Measurements for a 95th percentile[5] 3-year-old's small and middle fingers were averaged and used to approximate the length of the index finger. The minimum hand-clearance measurement of a 5th percentile 3-month-old child was selected. These measurements were then used to define the dimensions of Probe A.

Similarly for the 3-year to 8-year age group, measurements for the small and middle fingers of a 5th percentile child 37–42 months of age were averaged to approximate the diameter of the index finger. Measurements for the small and middle fingers of a 95th percentile child 85–96 months of age were averaged and used to approximate the length of the index finger. The minimum hand-clearance dimensions for a 5th percentile child 37–42 months of age were selected. These dimensions were then used to define the dimensions of Probe B.

Probe A determined the accessibility of edges in holes, recesses, or openings on toys intended for children 3 years of age or less. Probe B determined the accessibility of edges in holes, recesses, or openings on toys intended for children over 3 years up to 8 years of age.

Based on staff recommendations and the anthropometric measurements from the University of Michigan study on the physical characteristics of children (cited in Footnote 2, above) in the two age groups, the Commission defined accessibility for holes, recesses, and openings on toys and other children's articles as follows:

(1) *Finger access.* Section 1500.49(c)(3)(i) of the proposed regulation provided that access into openings which are large enough to accept a child's finger but too small to accept a child's hand would be determined by the appropriate accessibility probe.

Each of the two joints on a probe could be rotated up to 90 degrees to simulate knuckle movement and the total depth of insertion for accessibility would be up to the collar on the probe that is appropriate for either the 0 to 3-year age group (Probe A) or the 3-year to 8-year age group (Probe B).

The diameter of the collar on each probe was representative of the hand-clearance diameter of a 5th percentile child in the youngest age category within each age group. For the 0 to 3-year age group, the youngest age category is 0–3 months of age and for the 3-year to 8-year age group, the youngest age category is 37–42 months of age.

(2) *Hand access but not shoulder access.* Section 1500.49(c)(3)(ii) of the proposed regulation provided that access into openings large enough to accept a child's hand and arm but too small to admit the child's torso (body trunk) would be determined by the dimensions of the entrance of the opening. Such openings include openings that are larger than the width of a child's hand but smaller than the breadth of a child's shoulders. The Commission proposed that a depth-of-insertion factor of 2¼ multiplied by the minor dimension of an opening be used to determine the accessibility of edges in such openings.

The Commission defined a minor dimension of an opening as the diameter of the largest sphere that will pass

[3] All measurements were obtained from the University of Michigan's study, "Physical Characteristics of Children as Related to Death and Injury for Consumer Product Design and Use" (Highway Safety Research Institute, The University of Michigan, Ann Arbor, Mich. 48105).

[4] A 5th percentile 3-month-old child represents a child this age who is smaller than 95 percent and larger than 5 percent of children the same age.

[5] A 95th percentile 3-year-old child represents a child this age who is larger than 95 percent and smaller than 5 percent of children the same age.

through the opening, and it could be determined by using a pair of calipers. This dimension, multiplied by 2¼, determined the maximum depth of insertion for accessibility.

The value of 2¼ is the approximate average of the ratio of arm length to shoulder breadth for a 50th percentile child in each of the two age groups. For example, the depth of insertion into an opening with a minor dimension slightly smaller than the breadth of a child's shoulders will be slightly less than the length of the child's arm.

(3) *Total accessibility.* The Commission proposed that openings larger than the breadth of a child's shoulders should be considered totally accessible.

For the 0 to 3-year age group, the Commission selected a shoulder breadth measurement of 7.36 inches. This measurement represents a 5th percentile 1-year-old child, since children who are under 1-year of age are less mobile and therefore are less likely to climb into cavities than children who are 1-year of age or older.

For the 3-year to 8-year age group, the Commission selected a shoulder breadth measurement of 9 inches. This measurement represents a 5th percentile child in the age category of 37–42 months.

The Commission proposed that, for toys intended for children 0 to 3-years of age, access into openings with a minor dimension of 7.36 inches or larger would be considered totally accessible to a child. For toys intended for children 3 years to 8 years of age, access into openings with a minor dimension of 9 inches or larger would be considered totally accessible to a child. Because openings that are totally accessible to children in the 0–8 years age span may contain smaller openings that are not totally accessible to such children, access into these smaller openings would be determined by the appropriate procedures explained above.

(4) *Inaccessible edges.* From the results of sharp edge tests conducted on a representative sample of toys, the Commission observed that tabs and other protrusions or edges do not present a laceration or avulsion hazard if such protrusions or edges are flush with a protecting surface which is part of the toy. The Commission therefore decided that an edge should be considered inaccessible if it is protected by an adjacent surface and any gap between the edge and the adjacent surface does not exceed 0.020 inch.

(e) *Exemptions.* The proposed regulation exempted baby cribs and bicycles that are the subject of safety regulations already issued by the Commission under the FSHA (see 16 CFR 1500.18(a) (12), (13), and (14); 16 CFR Parts 1508, 1509, and 1512). These children's products, because they have already been addressed by the Commission in specific regulations, did not need to be addressed by the generic safety requirements for sharp edges.

Although the Commission had considered whether other children's products should be exempted from coverage, it decided in issuing the proposal that no other such exemptions were necessary or appropriate. Of course if any toy or children's article intended for children under 8 does not comply with the technical requirements but does not present a hazard, the Commission would not initiate any banning action against such an article.

The Commission included in the proposed technical requirements an exemption for children's products that have sharp edges by reason of their functional purpose (and that do not have any nonfunctional sharp edges). Toys with functional sharp edges, such as toy scissors and toy tool kits, were exempted as long as the toy was identified by a conspicuous, legible, and visible label as having a sharp edge(s). Other children's articles with functional sharp edges, such as children's ice skates and children's cutlery, were exempted and did not require any labeling.

In addition, the Commission discussed the applicability of the regulation to model and craft kits. Most children under 8 years of age do not have the dexterity and the reading ability necessary for assembling complicated model and craft kits, and such products in the marketplace today are usually not intended for children in the under 8 age category. Therefore, the Commission clarified that model and craft kits were excluded from the scope of the proposed regulation.

(f) *Preemption.* Whether a technical requirements regulation would preempt a State or local regulation that applies to sharp metal or glass edges on toys is a crucial issue. However, it is possible that the Commission's interpretation of the FHSA's preemption provision would not affect resolution of this question if a dispute arose. For example, if a State banned a toy and the manufacturer of the toy claimed that the State's authority was preempted by the existence of the Commission's regulation, the Commission would not necessarily be a party to any litigation or any out-of-court negotiation which might occur.

Nevertheless, the Commission interpreted the FHSA preemption provision (section 18 of the FHSA) and stated its view of how that provision would apply to a technical requirements regulation established to protect against the hazard of sharp metal or glass edges on toys intended for children under 8 years of age. The Commission's position, as stated in the September 1, 1977 FEDERAL REGISTER document, was that State and local governments would be prohibited from establishing or enforcing any nonidentical requirement that addresses the hazard of sharp metal or glass edges on toys intended for children under 8.

The Commission's proposed regulations are technical requirements that establish technical criteria for toys intended for children under 8. As long as States or local governments use these same criteria to regulate such toys, their requirements would be considered to be identical to the Commission's requirements, and thus not preempted according to the Commission's stated view of the preemption provision.

Even if a State or local government were to impose different penalties or use different procedures to regulate toys, there would be no preemption as long as the technical criteria were identical. As an example, if a State were to ban automatically any toy not meeting the criteria, such a ban would not be preempted by the Commission's technical requirements, according to the position taken by the Commission when it proposed the requirements in September 1977.

(g) *Effective date.* The regulation was proposed to become effective 365 days after its publication in final form in the FEDERAL REGISTER, and to apply to all products introduced into interstate commerce after that date.

The Commission further proposed that introduction into interstate commerce, for purposes of the regulation, be defined as follows: A toy manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy manufactured in the United States is introduced into interstate commerce: (a) At the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier.

(h) *Environmental considerations.* Before proposing the technical requirements regulation, the Commission assessed the environmental impact and concluded that no potentially significant environmental effects would be associated with the regulation. The Commission therefore found that there was no need for an environmental impact statement.

COMMENTS ON PROPOSAL

The Commission received 22 comments on its September 1977 proposal of a technical requirements regulation. Nineteen of these came from the industry, including comments from four trade associations, from individual toy manufacturers, and from a large retailer. In addition, an individual consumer, Consumers Union, and Underwriters Laboratories, Inc., commented

on the proposal. These comments are discussed below, according to the issues they address.

(a) *Procedures.* The banning procedure for toys which fail to meet the criteria and which the Commission believes present an unreasonable risk of injury is discussed in section (b) of this preamble under "Proposed Regulation." The procedure under the final regulation is the same as the procedure proposed in September 1977.

Before any toy can be banned, the Commission must notify those who would be affected by the ban, such as the manufacturer of the toy. The trade association Toy Manufacturers of America, Inc. (TMA), and other industry commenters have suggested that the notification be divided into two stages. They believe that manufacturers should be guaranteed a reasonable opportunity to respond to the Commission before any proposed ban is published in the FEDERAL REGISTER.

The Commission recognizes that a publicly proposed ban could adversely affect the marketability of a product, even if a final ban is never imposed. However, this factor must be balanced against the need for expeditious banning procedures. This need can be especially important because the current procedures already require a prescreening procedure (testing according to the technical requirements), a banning proposal, and a final ban to remove a product from the market.

Although the Commission may decide that prior notice to manufacturers of potentially hazardous toys would be fair and appropriate in particular circumstances, it does not believe that it should be restricted to this approach in all cases. If safety demands that a toy be removed from the market without any unnecessary delay, the Commission plans to notify affected persons individually or by FEDERAL REGISTER publication and then issue a final ban as soon as it has considered the comments received.

In a different comment concerning the procedures, a toy manufacturer has suggested that Commission staff opinions on the safety of new toys be easily obtainable. The enforcement staff is always available to discuss the applicability of the criteria to new toys, although it cannot, of course, provide premarket approval of toys or of any other product.

Finally, two commenters have pointed out that the Commission and its staff will evaluate toys that fail to meet the technical criteria in order to determine whether such toys should be the subject of banning procedures. These commenters have suggested that language be added to the regulation to identify some of the factors the Commission would use in this evaluation. Particular factors suggested were the location, accessibility, degree of sharpness, and length of the edge, as well as the likelihood of occurrence of an injury.

The Commission has no disagreement with the suitability of any of these factors for use in the evaluation process. However, this process is not within the scope of the technical requirements regulation issued below. As discussed in section (b) of the "Proposed Regulation" portion of this preamble, the first stage of the banning procedures involves compliance or non-compliance with the technical criteria of sharp metal or glass edges and is fully contained in the regulation. The second stage is the statutory banning proceeding that is governed by provisions of the FHSA and the Administrative Procedure Act.

The Commission has discussed the second stage rulemaking proceeding in this preamble and in the preamble to the proposed regulation in order to provide the perspective of how toys with sharp edges might be banned. However, the technical requirements regulation addresses only the first stage. Inclusion in this regulation of factors to be applied in the second stage would therefore be inappropriate and premature.

(b) *Sharp edge test criteria.* Nearly all of the industry commenters have criticized the sharp edge test method proposed by the Commission in September 1977. The comments pertaining to the test method and the Commission's responses are:

1. Comments. The test instrument is impractical, cumbersome, time consuming, unreasonably expensive, and incapable of being operated as a hand-held device. Further, the Commission's test data were accumulated on "precise fixture experiments" and would not correlate with the varying data anticipated from tests performed with hand-held instruments.

The Commission emphasizes at the outset that the sharp edge regulation does not require manufacturers to perform any tests on their toys. Rather, it specifies test criteria that the Commission will use to screen toys for potentially hazardous sharp edges. Of course the Commission does expect and encourage manufacturers to test their toys to assure compliance with the test criteria.

The regulation does not specify use of a hand-held test instrument or any other test instrument. The regulation does, however, reference engineering drawings for "a suitable portable sharp edge test instrument." The Commission may well test sharp edges by using the hand-held instrument described in these drawings. Commission staff persons have already performed many preliminary tests using an instrument manufactured according to these drawings.

A novice operator may encounter some of the particular testing problems cited by the commenters, such as the mandrel "kicking out and walking" when it begins its rotation. However, with a little practice an operator can perform the test in the manner intended. The Commission will not permit persons unfamiliar with the procedure to conduct tests on sharp edges which would be the basis of an ultimate toy ban.

Any difference in test results obtained from a hand-held sharp edge test instrument and those obtained from "precise fixture experiments" (bench tests) would, in the Commission's view, not be significant.

As to the costs of testing to manufacturers, the Commission anticipates that frequent testing of toys during a production cycle will not be necessary. This is true in part because many recent changes in the design of toys have already reduced the existence of potentially sharp edges.

Previously unprotected edges, which may not have complied with the criteria, have in many cases been eliminated by their concealment behind plastic molding or by hemming. For those toys on which it is not practical or economical to conceal edges, automated deburring processes have been introduced to dull the edges and eliminate laceration hazards. The Commission believes that an individual with some sharp edge test experience soon becomes able to touch an edge and determine whether there is any chance at all that it will not comply with the sharp edge test criteria. The use of such an informal test might well reduce the number of formal tests required to ascertain whether complying edges are being produced.

Finally, the Commission notes that none of the comments on the difficulties associated with the test instrument were accompanied by any test data to substantiate or provide specific instances of these difficulties.

2. Comments: The instrument is difficult to use and not totally consistent. The operator has exceptional difficulty in maintaining a constant 1.35 pounds force and, if the mandrel is not held exactly and steadily square to the sample, the cutting track is a wide line and the test results are both variable and invalid.

The Commission recognizes that the results of the sharp edge tests, like many laboratory procedures in common usage, may be materially influenced by operator technique. Despite these limitations, the Commission has confidence in the validity of the sharp edge test method as a screening procedure for sharp metal and glass edges on toys.

In testing edges, the Commission will calibrate any instrument it uses to be sure that no more than 1.35 pounds will be applied to the mandrel. This calibration will be checked periodically

and then verified before any toy is found to be in noncompliance with the technical criteria issued below. Section 1500.49(d)(2)(iii) has been modified to incorporate this principle.

In contrast, the Commission recommends that manufacturers using the sharp edge test method calibrate their instruments so that a force slightly greater than 1.35 pounds will be applied. This would provide the manufacturers with a margin of safety and an increased likelihood that their toys will comply with the test criteria.

The orientation of the test edge with respect to the mandrel involves at least two different variables. First, the line of the test edge and the mandrel axis must be positioned at 90 degrees ±5 degrees with respect to each other. Figure 1 of the regulation, as proposed and as issued below, illustrates this positioning. Even when Commission staff members used the hand-held instrument, they experienced no difficulty in maintaining the angle well within these specifications. The Commission will certainly insure that no toy will be banned if it has been identified as containing a sharp edge due to a deviation in the angle during the test procedure.

Second, the angle between the mandrel axis and the plane of the material on which the test edge is located is critical to the test results, because manufacturing processes can cause various types of edge conditions. For example, burrs on the edges of sheet metal toys produced by a punching process are generally at right angles to the plane of the metal. In contrast, flashing on the edges of metal toys produced by casting are generally in the plane of the metal forming the body of the toy. Therefore, the angle between the mandrel axis and the plane of the material cannot be specified in the regulation but should be varied by the test operator to seek the "worst case," the position at which the tape is most easily cut (as illustrated in Figure 1). The Commission believes that a manufacturer, who is aware of the fabrication process of the product, is in a better position to find this critical angle than the Commission's testing staff. It is therefore unlikely that the Commission will test and fail an edge which a manufacturer has tested and found satisfactory.

3. Comments: The test method is deficient because only one point on an edge, rather than the entire edge, is being tested. The rotating cylinder is unnecessarily complex and does not represent how a cutting injury usually occurs (it is more likely that a child's finger would be cut by moving along an edge than by a point on the edge moving around the finger).

During its development of the test method, the Commission considered but rejected the testing of a longer portion of an edge. In particular, the Commission does not believe that an alternative "wiping" test procedure—a procedure in which there is linear motion of a mandrel along the line of an edge, such as the one submitted by Underwriters Laboratories Inc.—is better than the procedure adopted by the Commission. In fact, NBS and CPSC staff persons were aware of the Underwriters Laboratories test method while they were developing the procedure issued below.

The Commission agrees that a "wiping" test more nearly simulates the injury pattern of the majority of cuts than the rotating mandrel. Nevertheless, the rotating mandrel is a more versatile and adaptable procedure because a "wiping" test can be applied only to relatively straight and long edges and many of the toys that are within the scope of the regulation are small and/or contain short edges. In distinguishing between sharp and dull edges, the Commission believes that the correlation between its rotating mandrel test and a "wiping" test would be high.

The commission notes that the "worst case" point on an edge should be tested by the rotating mandrel. Various points along an edge might, when tested, give different test results, and the point on an edge that seems most likely to cut the tape should therefore be tested.

4. Comment: It is impossible to keep the mandrel free of nicks and burrs, as the regulation requires, because an edge that cuts the tape "inevitably scratches the mandrel."

In the many tests conducted by the Commission staff, there has been no evidence of scratching or burring. This is true even though many of these tests were conducted with hardened steel edges and not the softer steel and other metals commonly used in the manufacture of toys. Scratching of a mandrel could result from its not having a minimum hardness of 40 on the Rockwell "C" scale, as specified in the regulation.

5. Comment: The tape specified in the test procedure is so sensitive that it repeatedly tears while being removed from the mandrel.

The Commission staff, in conducting many sharp edge tests using the procedure specified in the regulation, has not experienced this problem. If the tape appears to tear while being removed from the mandrel, it has, in all likelihood, been cut by the sharp edge being tested. The Commission staff has not observed cuts which are less than the full thickness of the tape. The tape is either grooved by the edge (no cut) or it is cut through the full thickness. In the Commission's experience, a tape sample which has been merely grooved has not shown any tendency to tear when removed from the mandrel.

6. Comments: The test procedure leads to subjective results because the tape is unreliable. In fact, the Commission itself has pointed out that in 10 percent of the cases repeatability of result was not attained.

Only with edges at the borderline between sharp and dull does the Commission believe that the tape may be cut in some cases and not in others. It is in part for this reason that noncompliance of an edge with the test procedure is never the sole factor supporting the ban of a toy.

As to the 10 percent statistic, the commenter does not cite the source and neither the Commission nor its staff is aware of ever making a statement like this. The commenter may be referring to the following statement contained in a staff memo: "One is 95 percent certain that no more than 5 percent of the tapes in the population are more sensitive than the most sensitive tape in the sample." If so, there is some confusion between repeatability and confidence. It is inappropriate to infer from this statement that re- peatability of result was not attained for 5 percent of the tapes (and certainly not for 10 percent of the tapes).

7. Comment: The test procedure specifies use of CHR type "T" tape manufactured by The Connecticut Hard Rubber Co. This violates all procurement requirements of the Federal Governmnent and "raises a serious question of propriety in the government direction of the private sector to a sole source procurement."

The test procedure calls for the use of tape meeting certain generic specifications. For the convenience of manufacturers and others who may want to test toys for sharp edges, the Commission has footnoted the brand of tape that it intends to use in its testing. This does not mean that no other brand of tape is acceptable or that no other brand meets the specifications in the regulation.

Since manufacturers need not test at all, they are certainly not required to use a particular brand of tape. There is no valid question of propriety because the Commission did not single out one brand of tape to the exclusion of others. In addition, the references in the comment to Federal procurement requirements are inappropriate because no Federal procurement is involved.

8. Comment: It will be difficult to obtain the tape since it can be supplied by just one source.

The tape referenced in the regulation is available through a distributor network in 35 States in the United States and through 12 distributors in foreign countries. Many major cities in the United States have several distributors. The availability of this product should therefore present no difficulty to anyone who wishes to purchase it.

If anyone does have difficulty finding the tape, the Commission's Office of the Secretary can supply a list of distributors.

9. Comment: Serious consideration should be given to the durability of the tape.

If this comment refers to the consistency of results over the expected life of a roll of tape, tests conducted by the Commission on a sample of tape rolls in 1975 are relevant. Date codes on the rolls of tape in this sample showed that 5 years of production were represented. Tests conducted to observe the consistency with which tapes in the sample were cut by a standard edge did not show any noticeable aging effects. Rather than relying solely on these tests, the Commission will use tape manufactured within a time period of no longer than 2 years when it tests edges for compliance with the technical criteria.

10. Comment: Figure 1 of the regulation ("Principle of Sharp Edge Test") should specifically reference the engineering drawings on file with the Commission.

Figure 1 is intended to clarify the principle of the sharp edge test method included in the regulation. In particular, it clarifies the proper angular position of the mandrel with respect to the test edge. As long as the sharp edge test method principles are followed, any device may be used. (As stated above, manufacturers need not test at all.)

In a footnote to the proposed regulation, and now in the text of the final regulation issued below, engineering drawings for a suitable sharp edge test instrument are referenced. The Commission stresses that this is not the only suitable instrument for sharp edge testing by the Commission or by manufacturers.

In an attempt to clear up any ambiguities, the Commission has modified the device sketched in Figure 1 so that it is no longer has a handle and so that it is labeled as "any suitable device, portable or non-portable, to apply known force and rotation to mandrel."

(c) *Accessibility criteria.* 1. Consumers Union (CU) has commented in some detail about the accessibility probes that are incorporated into the test criteria at section 1500.49(c), and has suggested the following:

A. Taper the finger portion of the probe (a) to correspond with the cross sectional dimensions that vary and (b) to be equated with the 5th percentile of the respective age group.

B. Taper the transition area, from the finger to the hand, to reflect more accurately the contour of the hand. CU has stated that the values of 1.02 inches and 1.51 inches (for hand clearance in the two age groups) seem to be too large for the dimension representing the region of the hand, where the third joint of the finger joins the hand.

C. Insert the probe, during testing, into the test openings with a force representative of the amount of force that children of the respective age groups may be expected to exert.

D. Articulate the probes at the junction of the finger to the hand and at the junction of the hand to the extension.

In addition, Consumers Union does not find any realistic relationship between the minor dimension of the opening multiplied by 2¼ and the depth to which a child may insert his or her fingers, hand, and arm through an opening. Practical observations by CU indicate that a 4½-year-old child could insert his or her hand and arm a distance of 9.7 inches through a 1¾-inch-wide opening and a distance of 16.5 inches, i.e. to the shoulder (torso) through a 2-inch-wide opening. Based on these observations, the multiplication factors should be 5.5 and 8.3, respectively.

CU has concluded that the probes should be revised dimensionally and, with regard to articulation, should more accurately simulate the finger, hand, and arm of the respective age ranges of children. CU also believes that the probe should be inserted into openings under evaluation as far as possible, in all directions possible, and at all degrees of articulation. If force of insertion causes flexing that may expose sharp edges to contact, then insertion should be made with forces suitable for each age group.

For a number of reasons, the Commission does not believe that any changes in the probes or the accessibility criteria are necessary.

The development of the accessibility probes proposed in September 1977 was conducted in response to a number of comments on the January 1975 proposal. Those comments stated that any probe should be based solely on child anthropometric data and not on data which incorporated adult dimensions.

Child dimensional data were available for the fingers, hand, and arm. However, it is obvious that children in the age range of concern, 0–8 years, become larger as they get older. Therefore, the problem of setting dimensions for accessibility is a dynamic one. One must first choose a small age range for which the dimensions are desired and then decide what percentile within that group would be appropriate. It immediately becomes apparent that for a given percentile in a set of data, the selected dimension will increase as age increases.

With the above background points in mind, the Commission considered the problem of constructing a device which simulates the finger of a 95th percentile child. Since the device must have only one dimension each for length and diameter, it becomes necessary to select these single dimensions from the data. In order to construct the test device, the Commission made the following determination:

Only two probes should be used, one each for the age spans of 0–3 years and over 3 and up to 8 years. This was done in the interests of simplicity and economy. Rather than build eight probes based on data at yearly increments, the Commission decided that two probes would be sufficient to cover the age ranges. The division point of 3 years was selected to correspond with that established in the already-issued Commission use and abuse testing procedures (16 CFR 1500.50–53). To select another division point would have simply added confusion to the Commission's overall toy safety program.

The Commission believes that adoption of CU's first two suggestions would conflict with the philosophy behind the probes which is reasonable representation and simplicity. With the use of the extreme dimensions within each range there is no advantage to tapering the probes at any particular place. Tapering would not resolve the basic problem of which dimension should be required. Further, tapering the probes would add to the cost of fabrication without adding any appreciable degree of safety.

Adoption of CU's suggestion that the probe be inserted with a force appropriate to the respective age group would add substantially to the complexity of screening toys for accessible sharp edges. To accomplish this suggestion would require a force transducer in series with the probe and the suspected sharp edge. This added feature would complicate the probe and substantially raise its cost without adding any measurable degree of safety. The suggestion is therefore rejected.

With regard to articulation of the probe at the junction of the finger to the hand, very little safety would be gained for the added cost of fabrication and complexity. The existing probes have the capability of flexing through an arc of 180 degrees. The suggested change would add 90 degrees to this capability after certain engineering changes. In only one instance would this capability be useful. This would be an opening through which a child would curl his finger as in making a fist and then have sufficient strength left to puncture the skin. The Commission does not believe the situation occurs with frequency sufficient to justify the addition. For the same reason, the Commission is rejecting the suggestion for articulation at the wrist.

Finally, CU has contended that there is no rationale for the 2.25 mul-

tiplication factor with regard to large openings. This multiplication factor was derived from the ratio between a child's arm length and shoulder breadth and was found to be approximately 2.25 for children in any age group between 1 and 8 years of age. The Commission wishes to point out that if an opening is large enough to permit entry of a child's hand, the depth to which the child could reach would be equal to the child's arm length. However, in its efforts to derive accessibility criteria which are reasonable and which reflect the probable actions of the majority of children, the Commission believes that the location of sharp edges subject to the test should be related to the size of the entrance of the opening. The Commission therefore finds that the 2.25 multiplication factor is reasonable and, in the absence of further information to guide the Commission, there is no compelling argument to change the multiplication factor to another quantity.

2. Other commenters have suggested some clarifying language changes to the provision of the proposed regulation concerning inaccessible edges (section 1500.49(c)(4)). The suggestions are to add the word "inside" to the definition of the edge considered inaccessible and to delete a sentence which provides an example of an inaccessible edge.

If the Commission correctly understands these suggested language changes, their adoption could modify the substance of the regulation rather than clarify its meaning. Therefore, a discussion of the "inaccessible edge" provision of the regulation, with particular reference to Illustration 1, might be helpful as a response to the comment.

A piece of metal used in a toy, as an example, will have more than one edge if it has any appreciable thickness. In this situation, only the edge closest to the protecting surface will be considered inaccessible under this provision, if the gap between the edge and the surface is no greater than 0.020 inches. In the example sketched in Illustration 1, this would apply to Edge A, an "inside" edge. In contrast, Edge B in the illustration would be unaffected by the provision. Regardless of the size of the gap, Edge B would be considered accessible.

The Commission rejects the suggested language changes because they do not clarify the inaccessible edge provision. However, the Commission has added to the provision a second example of an inaccessible edge with the hope that it will clarify the intent and effect of the provision. The example included in the proposed regulation concerned a lap joint. The new example concerns a hemmed edge such as the one in Illustration 1.

3. Two commenters have raised as an issue the accessibility of edges on toys that are sold in an unassembled state. They suggest that the following language be added to the regulation: "Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult."

The identical language is contained in the Commission's use and abuse regulations (16 CFR 1500.50(b)(5)) to prescribe how the use and abuse test procedures will be applied to toys not intended to be handled in their unassembled state by children.

The sharp edge regulation addresses injuries which occur to children during their casual handling of toys. In the Commission's view, such handling does not include their assembly of a toy which is intended to be assembled by an adult. The Commission further believes that appropriate cautionary labeling will sufficiently reduce the risk posed to a child from assembly of such toys. In most cases a parent or other adult—either as a purchaser of the toy or as a supervisor of the child—can be expected to heed the warning and assemble the toy before giving it to a child under 8 years of age.

The sentence suggested by the commenters has therefore been added to § 1500.49(c)(1) of the regulation, as issued below.

(d) *Applicability.* 1. Various manufacturers and TMA have supported exemptions for various products, including: replicas of real-life devices that are neither model nor craft kits; sporting goods, camping goods, and athletic equipment; musical instruments and furniture (but not toys which are counterparts of such products); playground equipment; and kites. TMA has mentioned that its voluntary standard PS 72-76 excludes most of the above products, and has asserted that the listed products are not intended to be covered by the Commission's regulation.

The Commission, as stated clearly in the preamble to the September 1977 proposed regulation, does intend the regulation to include other articles intended for use by children under 8 years of age, as well as toys. The only intended exemptions and exclusions have been discussed in section (e) of this preamble under "Proposed Regulation." If the Commission did exempt a wide variety of products, as suggested, the purpose and effectiveness of a generic regulation would be defeated. In fact, one of the reasons for changing the "self-executing" regulatory approach was to issue a broad generic regulation that applies to nearly all of the numerous products comprising the play environment of children from birth to 8 years. In addition, the Commission has received specific reports of laceration and avulsion injuries to children under 8 years of age involving children's furniture, playground equipment, kites, and science kits.

With regard to TMA's request for an exemption for musical instruments, the Commission believes that full-size real-life musical instruments are not within the scope of the regulation, even though they could occasionally be used by children under 8 years of age. Therefore, no exemption for such instruments has been added. Toy musical instruments and real-life musical instruments that because of their smaller size are intended primarily for children under 8, however, are clearly within the scope of the regulation.

A commenter has suggested that model and craft kits be exempted from the regulation. However, as discussed in section (e) under "Proposed Regulation" in this preamble, the Commission does not believe that these products are within the scope of the regulation. An exemption for model and craft kits is therefore unnecessary.

2. TMA has requested that the regulation include a formal exemption procedure for future use. Since the regulation can be amended according to the informal notice and comment rulemaking procedures of the Administrative Procedure Act, the Commission intends that this would be the procedure for exempting any products it subsequently believes should be exempt from coverage. Any interested person may, of course, petition the Commission to amend the regulation to exempt products from coverage.

3. A trade association of the bulk vending industry has commented that many of the technical requirements would not apply to the toys with which this industry is associated. The only stated support for this view is that such toys are "quite small in order that they may be dispensed through a bulk vending machine."

The Commission fails to see any connection between size and applicability of the regulation issued below. Unless exempted or excluded for some other reason, bulk vending machine toys are subject to the regulation if they are intended for children under 8 years of age.

(e) *Preemption.* As discussed in the preamble to the September 1977 FEDERAL REGISTER proposal and as discussed in section (f) under "Proposed Regulation" in this preamble, the Commission believes that State and local regulations would not be prempted by a technical requirements regulation, as long as they use the identical technical criteria. The use of different procedures by State and local govern-

ments, including an automatic banning approach for toys not meeting the criteria, would not change this result.

Nearly all of the industry commenters disagreed with this portion of the Commission's interpretation of the preemptive effect of the regulation issued below. They cited and discussed the legislative history of the FHSA preemption provision to show the congressional intent that State and local governments should be prohibited from addressing the same risk of injury in a different manner than the Federal Government. Chaos and a severe economic impact would result from the Commission's position, in the opinion of the industry commenters.

The Commission agrees that Congress intended manufactureres to be protected from the difficult task of complying with different manufacturing criteria in different parts of the country. As Senator Moss stated, in legislative history cited by TMA in its comments, "* * * to the extent possible, manufacuturers who produce products for a national market should be require to comply with only national standards" (Cong. Rec., April 28, 1976, page 56147, Col. 3, daily edition). It is partly for this reason that the Commission interprets the FHSA preemption provision as preventing State and local governments from using nonidentical technical criteria.

Under the Commission's interpretation of preemption, manufacturers can rely on the technical criteria set forth in the regulation below. No State or locality could use differing criteria to ban, because of sharp metal or glass edges, a toy intended for children under 8 years of age. Despite the strong and articulate comments submitted by the industry, however, the Commission still does not believe that the FHSA preemption provision prohibits States and localities from using different procedures in conjunction with the technical criteria. FHSA preemption applies only to "requirements" and the Commission's two-stage banning approach is neither included in nor required by the technical requirements regulation issued below.

Nevertheless, the Commission believes that the technical requirements regulation should not be used to ban automatically all toys not meeting the technical criteria. As a matter of public responsibility and of fairness, a regulatory body should evaluate the hazard presented by any toy which fails to meet the technical criteria before banning that toy.

The Commission's two-stage banning procedure, which provides an opportunity for considering the comments of the affected industry prior to banning, guarantees this responsibility and fairness at the Federal level. The Commission strongly encourages the use of the same or similar procedures at the State and local levels prior to the banning of any toy intended for use by children under 8 years of age that contains sharp metal or glass edges.

In addition to the many commenters who disagreed with the Commission's proposed preemption position, one commenter asserted that the Commission should not discuss preemption at all. This commenter characterized the Commission's interpretation of the FHSA preemption provision as unnecessary and noted that it could lead to "confusion, disruption, and perhaps unnecessary litigation."

The Commission recognizes that its interpretation of the FHSA preemption provision would not be binding on a court in which the industry and a State or local government are litigating the preemptive effect of the regulation issued below or of any other FHSA regulation. In fact, the Commission considered the possibility of taking no position on preemption for this reason.

However, the Commission administers the FHSA and believes that it should not remain silent when a matter of FHSA statutory interpretation is affected but unfesolved by a Commission action. This is especially true where the Commission has proposed a statutory interpretation and has received many public comments on it.

(f) *Effective date.* The Commission has received one comment on its proposal that the regulation become effective 365 days from the date of its publication in the FEDERAL REGISTER. A toy manufacturer has termed this proposal "an effective date that will afford a reasonable opportunity for affected manufacturers to revise their tooling and packaging." However, this manufacturer then states that, because the technical requirements for sharp edges and sharp points are inseparable, neither regulation should become effective until the other is finalized and effective. (The Commission published a sharp point regulation in final form in the FEDERAL REGISTER on December 22, 1977 (42 FR 64288) and it becomes effective on December 22, 1978.)

The Commission believes that the sharp edge and sharp point regulations are related but not "inseparable." No other manufacturer has indicated that a 1-year effective date for the regulation issued below cannot be met. The Commission still believes that a full year of lead time is ample and fair, even though the sharp point regulation will become effective prior to the effective date for the sharp edge regulation.

Accordingly, all products introduced into interstate commerce after March 26, 1979 are subject to the sharp edge regulation issued below. The Commission has incorporated into the regulation the applicable definition of introduction into interstate commerce.

(g) ECONOMIC CONSIDERATIONS

A number of commenters have claimed that the regulation will cause substantially higher retail prices for toys and that it discriminates against manufacturers of metal and glass toys.

The Commission's economics staff has surveyed the market and analyzed the expected economic impact of the sharp edge regulation on manufacturers of toys and other children's articles, including those made from metal and glass. Based on this information, contained in an April 1977 report that is available from the Office of the Secretary, the Commission believes that a wide range of products will be affected but that price increases caused by the regulation will be small. The Commission expects the economic impact of the regulation on individual manufacturers to vary, depending on such factors as the type of article produced, the size of the product line, the number of products needing production changes, and the existing state of compliance with the regulation.

Because edges made of materials other than metal and glass cannot be meaningfully evaluated by the sharp edge test method issued below, the regulation addresses only metal and glass edges. However, the National Bureau of Standards is continuing its research on sharp edges, on behalf of the Commission, in an attempt to develop a meaningful test procedure for plastics and for other materials. If and when such a procedure is available, the Commission intends to regulate edges made of materials other than metal and glass.

In issuing a regulation that extends only as far as current technology permits, the Commission does not believe that it has discriminated against the manufacturers of products covered by the regulation. The illogic of the alternative approach is clear. The Commission would have to withhold all safety regulations until it is ready to regulate simultaneously every product within its jurisdiction.

(h) *Environmental considerations.* The Commission has received no comments on the environmental impact of the regulation or on its decision that there is no need for an environmental impact statement.

(i) *Miscellaneous.* 1. TMA has suggested that the Commission reference section 2(q) of the FHSA as authority for issuing the technical requirements regulation. As TMA has pointed out, the Commission's preemption position makes clear its view that the regulation is issued for the enforcement of section 2(q). Nevertheless, the regulation is authorized by section 10(a),

which authorizes regulations "for the efficient enforcement" of the FHSA, and section 2(s), which defines articles that are "mechanical hazards." Section 2(q) defines "banned hazardous substances" and the regulation issued below does not ban any product. The suggestion is therefore rejected.

2. A consumer has questioned the need for the proposed regulation and has asserted that consumers should be free "to try different things and make their own mistakes." The Commission believes that the existing hazard data support the need to reduce the potential unreasonable risk of injury associated with certain sharp metal or glass edges on toys. Especially since children are the victims of these injuries, the Commission disagrees with the suggestion that it let consumers make their own mistakes rather than try to reduce or prevent injuries.

FINAL REGULATION

The regulation issued below addresses the hazard presented by toys, intended for children under 8 years of age, which contain sharp glass edges. This is the same hazard which the Food and Drug Administration (FDA) addressed in 1973 by proposing to ban under the FHSA certain toys or other children's articles containing glass (38 FR 9310-11, April 13, 1973). (Before the Commission was established, the FDA administered the FHSA.) Because the FDA proposal has been superseded by the regulation issued below, it is hereby withdrawn.

Although it was not the subject of any comments from the public, the Commission has noted that certain language in the regulation, as proposed in September 1977, was repetitious. The second sentence in the section 1500.49(b)(1) provision on the scope of the regulation described the application of the use and abuse tests to sample edges. Equivalent language is contained in the 1500.49(c)(1) provision on accessibility. The Commission believes that the sentence in the scope provision is unnecessary and it has been deleted from the final regulation.

In addition, the Commission restates that English figures are used throughout the regulation. Their metric approximations are included in parentheses for convenience and information only.

With the exception of the changes discussed in this preamble and editorial changes, the final technical requirements regulation is identical to the September 1977 proposal. Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269)), in accordance with the provisions of 5 U.S.C. 553, and under authority vested in the Commission by the Consumer Product Safety Act (Pub. L. 92-753, sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a))), the Commission amends 16 CFR Part 1500 by adding a new § 1500.49, as follows:

§ 1500.49 Technical requirements for determining a sharp metal or glass edge in toys and other articles intended for use by children under 8 years of age.

(a) *Objective.* The sharp edge test method prescribed by paragraph (d) of this section will be used by the Commission in making a preliminary determination that metal or glass edges on toys and other articles intended for use by children under 8 years of age, and such edges exposed in normal use or as a result of reasonably forseeable damage or abuse of such toys and articles, present a potential risk of injury by laceration or avulsion under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate toys and other articles with edges that are identified as presenting a potential risk of laceration or avulsion injury to determine the need for individual product regulation.

(b) *Scope*—(1) *General.* The sharp edge test of paragraph (d) of this section is applicable to toys or other articles containing metal or glass edges that are introduced into interstate commerce after March 26, 1979. Such articles manufactured outside the United States are introduced into interstate commerce when first brought within as U.S. port of entry. Such articles manufactured in the United States are introduced into interstate commerce (a) at the time of first interstate sale, or (b) at the time of first intrastate sale if one or more components and/or raw materials were received interstate, whichever occurs earlier.

(2) *Exemptions.* (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this § 1500.49: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (Parts 1508, 1509, and 1512 of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any nonfunctional sharp metal or glass edges are exempt from this section: Provided, the toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp metal or glass edges. Examples of these are a pair of toy scissors and toy tool kits.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any non-functional sharp metal or glass edges are exempt from this section. Examples of these are children's ice skates and children's cutlery.

(3) *Definitions*—(i) *Glass.* For the purpose of this regulation the Commission defines glass as a hard, brittle, amorphous substance produced by fusion, usually consisting of mutually dissolved silica and silicates that also contain soda and lime.

(ii) *Metal.* For the purpose of this regulation the Commission intends the word metal to include both elemental metals and metal alloys.

(c) *Accessibility.*—(1) *General.* Any metal or glass edge that is accessible either before or after the test of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp edge test of paragraph (d) of this section. Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult.

(2) *Accessible edges.* (i) An accessible metal or glass edge for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in Figure 2 of this section.

(ii) An accessible edge for a toy or article intended for children over 3 years and up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as Probe B in Figure 2 of this section.

(iii) An accessible edge for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either Probe A or Probe B, as shown in Figure 2 of this section.

(3) *Insertion depth.* (i) For any hole, recess, or opening having a minor dimension (the minor dimension of an opening is the diameter of the largest sphere that will pass through the opening), smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of Probe A, but less than 7.36 inches (186.9 millimeters), when Probe A is used, or a minor dimension larger than the collar diameter of Probe B, but less than 9 inches (228.6 millimeters), when Probe B is used, the total insertion depth for accessibility shall be determined by inserting the appropriate probe with the extension, shown in Figure 2, in any direction up to 2¼ times the minor dimension of the hole, recess, or opening, measured from any point in the

plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when Probe A is used, or a minor dimension of 9 inches (228.6 millimeters) or larger when Probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that in 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible edges.* Metal or glass edges shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample, and any gap between the edge and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) both before and after the tests of 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed. For example, in a lap joint in which a metal edge is overlapped by a parallel surface, any burr or feather-edge on the side closest to the protecting parallel surface is considered inaccessible if the gap between the edge and the parallel surface is no greater than 0.020 inch (0.50 millimeter). As an additional example, when sheet metal has a hemmed edge a portion of the sheet adjacent to the edge is folded back upon itself, approximately 180 degrees, so that it is roughly parallel to the main sheet. Any burrs or feathering on the inside edge, the side closest to the protecting parallel surface of the main sheet, will be considered inaccessible if the gap between the inside edge and the parallel surface does not exceed 0.020 inch (0.50 millimeter).

(d) *Sharp edge test method.*—(1) *Principle of operation.* The test shall be performed with a sharp edge tester which contains a cylindrical mandrel capable of rotation at a constant velocity. (Engineering drawings for a suitable portable sharp edge test instrument are available from the Commission's Office of the Secretary.) The full circumference of the mandrel shall be wrapped with a single layer of polytetrafluoroethylene (TFE) tape as specified in paragraph (e)(3) of this section. The mandrel shall be applied to the edge to be tested with a normal force of 1.35 pounds (6 Newtons) such that the edge contacts the approximate center of the width of the tape as shown in Figure 1 of this section. The mandrel shall be rotated through one complete revolution while maintaining the force against the edge constant. Linear motion of the mandrel along the line of the edge shall be prevented. The edge shall be identified as sharp if it completely cuts through the tape for a length of not less than ⅛ inch (13 millimeters) at any force up to 1.35 pounds (6 Newtons).

(2) *Procedure* (i) The edge of the sample to be tested shall be held in such a manner that it does not move during the test. If the full mandrel force of 1.35 pounds (6 Newtons) causes the edge to bend, a reduced mandrel force may be used.

(ii) Part of the test sample may need to be removed to allow the sharp edge testing device to test an edge that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the edge in question. The sharp edge test shall be performed with the edge supported so that its stiffness approximates but is not greater than the edge stiffness in the assembled sample.

(iii) Conduct of a sharp edge test is as follows: Wrap one layer of polytetrafluoroethylene (TFE) tape, described in paragraph (e)(3) of this section, around the full circumference of the mandrel in an unstretched state. The ends of the tape shall be either butted or overlapped not more than 0.10 inch (2.5 millimeters). Apply the mandrel, at the approximate center of the tape, to the edge of the test sample with a force of 1.35 pounds (6 Newtons) measured in a direction at right angles to the mandrel axis. The mandrel shall be placed so that its axis is at 90 degrees ±5 degrees to the line of a straight test edge or 90 degrees ±5 degrees to a tangent at the point of contact with a curved test edge. The point of contact between the test edge and the mandrel shall be in the approximate center of the width of the tape. The axis of the mandrel may be positioned anywhere in a plane which is at right angles to either the line of a straight test edge or to a tangent at the point of contact with a curved test edge. The operator should seek the orientation most likely to cause the edge to cut the tape. Maintain the force against the edge and rotate the mandrel through one complete revolution while preventing any linear motion of the mandrel along the edge. Release the mandrel from the edge and remove the tape without enlarging any cut or causing any score to become a cut. A cut in the tape with a length of not less than ⅛ inch (13 millimeters) identifies an edge as sharp. (The test instruments used by the Commission in its test for compliance with the regulation will be calibrated to insure that the force with which the mandrel is applied to a test edge does not exceed 1.35 pounds.)

(e) *Specifications for sharp edge test equipment.* The following specifications shall apply to the equipment to be used in the sharp edge test described in paragraph (d) of this section:

(1) The rotation of the mandrel shall produce a constant tangential velocity of 1±0.08 inch per second (25.4±2 millimeters per second) during the center 75 percent of its rotation and shall have a smooth start and stop.

(2) The mandrel shall be made of steel. The test surface of the mandrel shall be free of scratches, nicks, or burrs and shall have a surface roughness no greater than 16 microinches (0.40 micron). The test surface shall have a hardness no less than 40 as measured on the Rockwell "C" scale, as determined pursuant to ASTM E 18-74 entitled "Standard Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials," published July 1974 and which is incorporated by reference in this regulation.[1]

(3) The tape shall be pressure-sensitive polytetrafluoroethylene (TFE) high temperature electrical insulation tape as described in Military Specification MIL-I-23594B (1971) which is incorporated by reference in this regulation.[1] (Copies are available from Naval Publications and Forms Center, 5801 Tabor Ave., Philadelphia, Pa. 19120.) The thickness of the poly- tetrafluoroethylene backing shall be between 0.0026 inch (0.066 millimeter) and 0.0035 inch (0.089 millimeter).[2] The adhesive shall be pressure-sensitive silicone polymer with a nominal thickness of 0.003 inch (.08 millimeter). The width of the tape shall not be less than ¼ inch (6 millimeters). While

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[1]Incorporation by reference provisions approved by the Director of the Federal Register, March 16, 1978, and copies of the incorporated material are on file in the Federal Register library. (Copies are available from American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.) The diameter of the mandrel shall be 0.375±0.005 inch (9.35±0.12 millimeters). The mandrel shall be of suitable length to carry out the test.

[2]The tape that the Commission will use for the sharp edge test is CHR type "T" manufactured by The Connecticut Hard Rubber Co., New and East Streets, New Haven, Conn. 06509.

conducting sharp edge tests the temperature of the tape shall be maintained between 70° F (21.1° C) and 80° F (26.6° C).

(f) For the purpose of conformance with the technical requirements prescribed by this § 1500.49, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

AUTHORITY: Secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269).

Dated: March 14, 1978.

SHELDON D. BUTTS,
Assistant Secretary, Consumer Product Safety Commission.

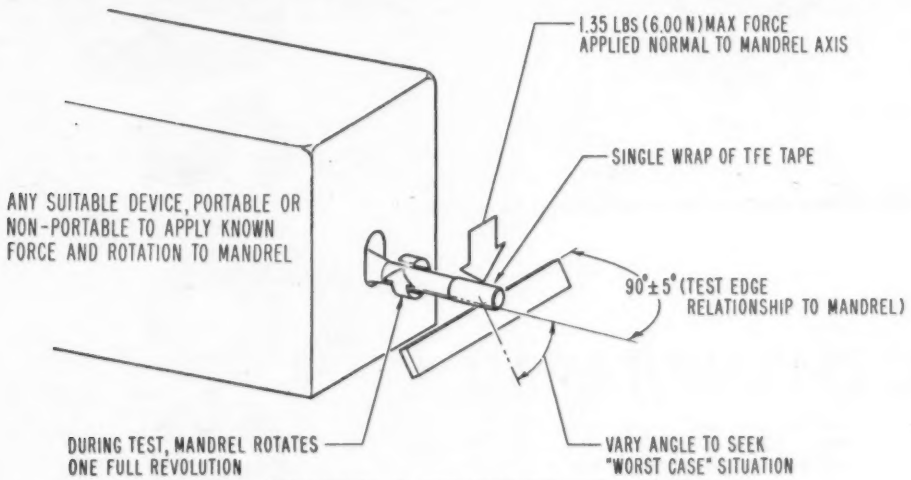
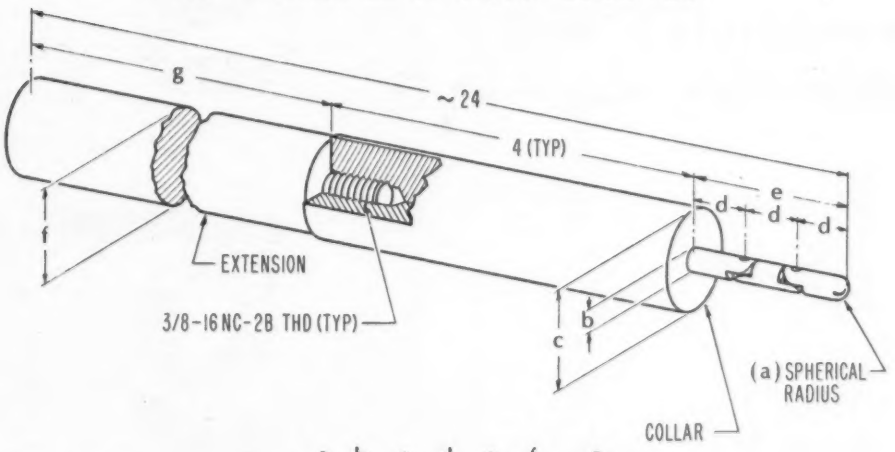

1.35 LBS (6.00 N) MAX FORCE APPLIED NORMAL TO MANDREL AXIS
SINGLE WRAP OF TFE TAPE
ANY SUITABLE DEVICE, PORTABLE OR NON-PORTABLE TO APPLY KNOWN FORCE AND ROTATION TO MANDREL
90°±5° (TEST EDGE RELATIONSHIP TO MANDREL)
DURING TEST, MANDREL ROTATES ONE FULL REVOLUTION
VARY ANGLE TO SEEK "WORST CASE" SITUATION

FIG 1—PRINCIPLE OF SHARP EDGE TEST



		a	b	c	d	e	f	g
(CHILDREN 0-36 MONTHS INCL)	PROBE A	110	220	1020	577	1.731	1	18 9/32
(" 37-96 " ")	PROBE B	170	340	1510	760	2.280	1 1/2	17 25/32

ALL DIMENSIONS IN INCHES

FIG 2—ACCESSIBILITY PROBES

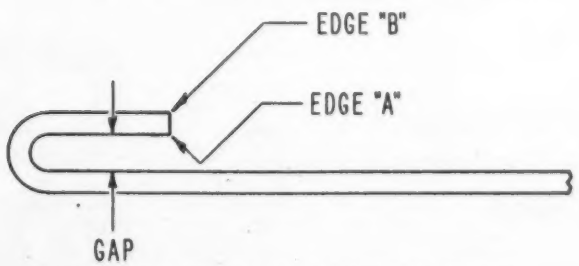


ILLUSTRATION 1—HEMMED EDGE

[FR Doc. 78-7689 Filed 3-23-78; 8:45 am]